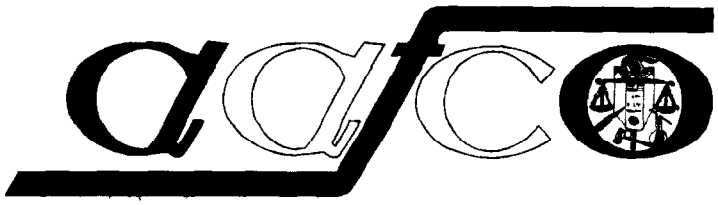

ASSOCIATION OF AMERICAN FEED CONTROL OFFICIALS, INC.

August 13, 2004

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, MD 20852

RE: Food and Drug Administration, Docket No. 2004N-0264

To Whom It May Concern:

On behalf of the Association of American Feed Control Officials (AAFCO), I wish to comment on the potential changes to the existing rule prohibiting the use of protein from certain mammalian tissues to prevent the establishment and amplification of bovine spongiform encephalopathy (BSE) in United States cattle. Solicitation for comment is from the advance notice of proposed rule making dated July 9, 2004, issued under sections 201, 402, 409, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, and 371) and under the authority of the Commissioner of Food and Drugs. AAFCO is an international association with membership consisting largely of state feed control officials responsible for administration of state laws, rules, and portions of the Food, Drug and Cosmetic Act pertaining to the distribution of commercial feed and feed ingredients for livestock, poultry and other animals, including pets.

Members of our association continue to conduct the majority of the inspections of the commercial feed manufacturing establishments in North America for compliance with the requirements of regulations designed to prevent the spread of BSE through feed. AAFCO is committed to ensure that the industry achieves 100% compliance with the federal rule as defined in Title 21, Code of Federal Regulations, Part 589.2000, prohibiting the feeding of protein from certain mammalian tissues to cattle and other ruminants, or appropriate regulatory compliance actions are taken. AAFCO presents the following responses to questions listed in the Federal Register identified under Docket No. 2004N-0264:

1. Animal Feed Restrictions Specified Risk Materials (SRMs)

> **Question:** What information, especially scientific data, is available to support or refute the assertion that removing SRMs from all animal feed is necessary to effectively reduce the risks of cross-contamination of ruminant feed or of feeding errors on the farm?
>
> **Response:** Banning the inclusion of these high-risk materials has the potential to positively impact both animal and human health as indicated in the Harvard Risk

2004N-0264

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Assessment and by the International Review Team (IRT).

Question What information is available on the occurrence of on-farm feeding errors or cross- contamination of ruminant feed with prohibited material?

Response: This information should be available through the BSE inspection and compliance data collected by FDA/ORA or individual states. Further inspection of on-farm feed manufacturers could also provide this data.

Question If SRMs are prohibited from animal feed, should the list of SRMs be the same list as for human food? What information is available to support having two different lists?

Response: It is imperative that any regulations developed to ban the inclusion of these materials are practical and enforceable and provide clear guidance to the slaughter and rendering industries as to the appropriate disposition of these materials and address other related issues including the rendering of non-ambulatory disabled animals.

Question What methods are available for verifying that a feed or feed ingredient does not contain SRMs?

Response: AAFCO is not aware of any methodology to determine the identity of SRMs after they have been rendered.

Question If SRMs are prohibited from animal feed, what requirements (labeling, marking, denaturing) should be implemented to prevent cross- contamination between SRM-free rendered material and material rendered from SRMs?

Response: Permanently marking or denaturing that can be verified through laboratory analysis is essential to prevent cross- contamination. In addition, dedicated facilities and equipment to process, store and convey this material would be necessary, combined with an inspection and monitoring system in place.

Question What would be the economic and environmental impacts of prohibiting SRMs from use in all animal feed?

Response: This question can be best answered by the affected industries, such as livestock production, rendering, feed and commercial waste disposal and perhaps the Environmental Protection Agency.

Question: What data are available on the extent of direct human exposure (contact, ingestion) to animal feed, including pet food? To the degree such exposure may occur, is it a relevant concern for supporting SRM removal from all animal feed?

Response: Public and animal health professionals can best answer this question.

2. Cross Contamination

Question What information, especially scientific data, is available to show that dedicated facilities, equipment, storage, and transportation are necessary to ensure that cross contamination is prevented? If FDA were to prohibit SRMs from being used in animal feed, would there be a need to require dedicated facilities, equipment, storage, and transportation? If so, what would be the scientific basis for such a prohibition?

Response: The intent and the objectives of the rule are best achieved when dedicated facilities, dedicated manufacturing equipment and dedicated conveyance and transportation equipment are utilized. When a facility making cattle or other ruminant feed does not handle prohibited material, the chance of commingling, contamination and accidental mixing or human errors is minimized. The AAFCO BSE policy statement encourages feed manufacturers and ruminant feeders to review, adopt and implement best management practices, such as those suggested by their trade associations, which go above and beyond the current requirements of the rule and can further minimize the potential of BSE becoming established in the United States.

Question: What information, especially scientific data, is available to demonstrate that clean-out would provide adequate protection against cross contamination if SRMs are excluded from all animal feed?

Response: Where dedicated facilities and equipment are not used, the Agency should mandate the validation of written clean-out procedures and record-keeping systems for all segments of the feed manufacturing industry including the distribution and transportation sectors. If there is adequate scientific support of a safe level of carryover for the BSE agent in ruminant feed, an established tolerance should be implemented by the FDA. If there is no adequate scientific support to establish this, there should be zero tolerance for the level of contaminant in the feed.

Question: What would be the economic and environmental impacts of requiring dedicated facilities, equipment, storage, and transportation?

Response: This question can be best answered by the affected industries, such as livestock production, rendering and feed.

3. Feed restrictions

Question: What information, especially scientific data, supports banning all mammalian and avian MBM in ruminant feed?

Response: AAFCO is not aware of specific scientific data that indicates the banning of all mammalian and avian derived proteins will reduce the spread of BSE. However, a broader ban on animal protein products will reduce the reliance on

inefficient analytical methods currently available to verify the sources of animal proteins in ruminant animal diets.

Question: If SRMs are required to be removed from all animal feed, what information, especially scientific data, is available to support the necessity to also prohibit all mammalian and avian MBM from ruminant feed, or to otherwise amend the existing ruminant feed rule?

Response: While SRM contain the highest concentration of infectivity, there is scientific data that supports the BSE agent may be present in other areas. Furthermore, there is no current analytical method to verify the source of proteins after they have been rendered. Therefore, interfering in the surveillance and enforcement of the use of prohibited animal proteins.

Question: What would be the economic and environmental impacts of prohibiting all mammalian and avian MBM from ruminant feed?

Response: This question can be best answered by the affected industries, such as the livestock production, rendering, feed and commercial waste disposal and perhaps the Environmental Protection Agency.

Question: Is there scientific evidence to show that the use of bovine blood or blood products in feed poses a risk of BSE transmission in cattle and other ruminants?

Response: Animal health professionals can best answer this question.

Question: What information is available to show that plate waste poses a risk of BSE transmission in cattle and other ruminants?

Response: Banning the inclusion of plate waste in cattle or other ruminant feed will eliminate another potential source of exposure. While consideration must be given to plate waste that does not contain ruminant material, it is imperative that any regulations developed to ban the inclusion of this material are practical and enforceable. If analytical methodology were developed to accurately detect ruminant protein in ruminant feed, allowing plate waste would make the test results inconclusive. A partial ban of plate waste feeding to cattle or other ruminants (e.g., allowing feeding of plate waste which does not contain ruminant material) would also be unenforceable and is not recommended.

Question: If FDA were to prohibit SRMs from being used in animal feed, would there be a need to prohibit the use of poultry litter in ruminant feed? If so, what would be the scientific basis for such a prohibition?

Response: Banning the inclusion of poultry litter in cattle or other ruminant feed will eliminate another potential source of incidental exposure of ruminant animals to prohibited protein from certain mammalian tissues due to the presence of spilled poultry feed in the litter which contains or may contain prohibited material. While consideration must be given to poultry litter that does not contain SRM, it is imperative that any regulations developed to ban the inclusion of this material are

practical and enforceable. A partial ban of poultry litter feeding (e.g., allowing feeding of poultry litter, which does not contain prohibited material) would be unenforceable and is not recommended.

Question: What would be the economic and environmental impacts of prohibiting bovine blood or blood products, plate waste, or poultry litter from ruminant feed?

Response: If poultry litter is banned as a feed ingredient, the impact on the use of poultry litter as a fertilizer/soil amendment must be considered. Currently, poultry litter is topically applied as a source of plant nutrients and organic matter on pastures and agronomic fields, often times at very high rates. Both livestock and wildlife have access to this material as a feed source under this practice. This material is not typically incorporated into the soil because of economic costs, though incorporation would increase plant nutrient benefit from this agronomic practice and reduce the exposure to livestock and wildlife. In States that have significant poultry production, the use of excess poultry litter has become a disposal issue, which has been compounded by nutrient management issues. Additionally, many States also lack the legal authority for on-farm inspections to determine and enforce compliance with regard to the feeding of poultry litter to cattle or other ruminants on-farm.

Question: Is there any information, especially scientific data, showing that tallow derived from the rendering of SRMs, dead stock, and non-ambulatory disabled cattle poses a significant risk of BSE transmission if the insoluble impurities level in the tallow is less than 0.15 percent?

Response: Animal health professionals can best answer this question.

4. Non-Ambulatory (Downer) Cattle

Question: Can SRMs be effectively removed from dead stock and non-ambulatory disabled cattle so that the remaining materials can be used in animal feed, or is it necessary to prohibit the entire carcass from dead stock and non-ambulatory disabled cattle from use in all animal feed?

Response: It is imperative that any regulations developed to ban the inclusion of these materials are practical and enforceable and provide clear guidance to dead animal collectors and renderers as to the appropriate receipt, processing and disposition of these materials. Since there are no known methods of analysis to recognize SRM from other rendered animal protein; a total ban might be appropriate, if these issues cannot be adequately addressed.

Question: What methods are available for verifying that a feed or feed ingredient does not contain materials from dead stock and non- ambulatory disabled cattle?

Response: AAFCO is not aware of any methodology to determine the identity of SRM after the rendering process has denatured them.

Question: What would be the economic and environmental impacts of prohibiting materials from dead stock and non-ambulatory disabled cattle from use in all animal feed?

Response: This question might be best answered by the rendering industry, in addition to experts from commercial waste disposal industry and perhaps the Environmental Protection Agency.

5. Disposal of SRMs and Non-Ambulatory Disabled Cattle

Question: What other innovative solutions could be explored?

Response: This question might be best answered by the rendering and commercial waste industries.

Depending on the potential changes to the feed ban, FDA should consider that requiring the BSE caution statement on pet food that contains or may contain prohibited protein would improve enforcement and compliance. Employees of the feed manufacturing sector, the retail and wholesale distribution sector and on-farm producers would be able to recognize that these products are clearly not intended for cattle or other ruminants. The inclusion of a warning statement on pet food could result in a temporary shift from prohibited protein material use in pet food, as consumers move to purchase pet foods without the caution statement and prohibited mammalian protein. This is an educational issue. A BSE regulatory program should not withhold information from distributors, feed manufacturers and customers, especially when some of the customers are livestock producers. Accurately labeling feed that contains or may contain prohibited mammalian protein to reflect that the pet food is not intended for cattle or other ruminants will help ensure that these products are handled and used appropriately in all sectors.

On behalf of the Association of American Feed Control Officials I would like to thank the Food and Drug Administration for the opportunity to provide these comments for your consideration.

Sincerely,

Philip K. Petry
AAFCO President